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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|---------------------|
| 10/519,654 | 08/19/2005 | Clay B Marsh | 18525/04133 | 7420 |
| 24024 | 7590 | 03/30/2006 | EXAMINER | |
| CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114 | | | | TRUONG, TAMTHOM NGO |
| ART UNIT | | PAPER NUMBER | | |
| | | 1624 | | |

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/519,654 | MARSH, CLAY B | |
| | Examiner Tamthom N. Truong | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12-22-04 (Pre. Amdt).
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 and 28-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 and 28-35 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6-24-05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's preliminary amendment of 12-22-04 is acknowledged and entered.

Claims 13-27 have been cancelled.

Claims 28-35 have been added.

Claims 1-12 and 28-35 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 and 28-35 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by **Zimmermann et. al.** (WO 99/03854 – cited on IDS).

On page 1, line 13, Zimmermann et. al. disclose the free base of the compound *4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimdin-2-ylamino]phenyl]-benzamide*, which is the same as the claimed Compound I. On page 4, the *monomethanesulfonate salt* of that compound is disclosed as formula II, which is the same as the salt recited in claim 3, which falls within the scope of claim 2. The disclosed compound and its salt are used to treat cancers as well as combating the haemotoxic effect of asthma, and treating diseases which respond to an inhibition of the PDGF receptor kinase (see page 11, lines 1-8 (first

paragraph)). Page 12 further relates the activity of the disclosed compound and its salt to the *synergistic effects with other immunomodulatory or anti-inflammatory substances*. Thus, by inference, the reference teaches anti-inflammatory effect to the disclosed compound and its salt. Furthermore, the term “comprising” in the instant claims does not limit to Compound I and/or its monomethanesulfonate salt.

The instant claims 4-6 and 28-33 which recite the limitations of *monocytes, M-CSF-stimulated monocytes, autoimmune diseases, arthritis, and lung injuries*. As disclosed in the “Background” of the invention, monocytes and M-CSF-stimulated monocytes are known to be involved in many inflammatory diseases. Therefore, it is understood that the *synergistic anti-inflammatory effect* of the disclosed compound and its salt would treat diseases where monocytes are involved such as: asthma, psoriasis, etc.

The instant claims 11, 12, 34 and 35 recite dosages which are disclosed on page 17, lines 14-16.

Thus, the reference’s disclosure inherently teach the method recited in claims 1-12 and 28-35

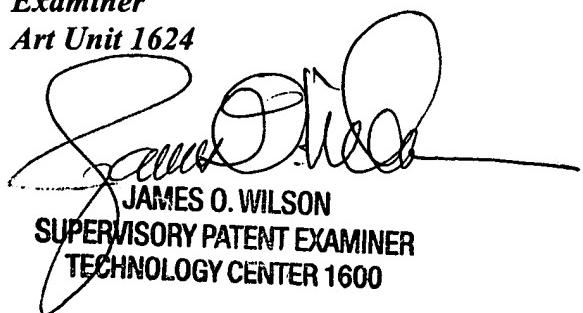
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3-18-06


Tamthom N. Truong
Examiner
Art Unit 1624


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600